King, Valerie A.

From: King, Valerie A.
Sent: Wednesday, April 30, 2003 1:38 PM
To: Nixon, Gerry M.; Schuster, Dave
Cc: Koller, Debbie; Werley, Michael S
Subject: RE: Input to Master Plan Template

Dave:
Let me clarify - my intent had been to suggest only the removal of the investigator's brochure task from our schedule, not the development of the study objectives or protocol summary (those should remain).

I am fine with leaving the IB in the Clinical schedule if it doesn't make sense to everyone to move it elsewhere. However, I need some input from Debbie/Mike to suggest a standard duration for the task and whether there are any predecessors to it in the existing schedule.

Gerry:
I agree with your comment about adding time for preparation of the test cigarettes in the clinical schedules - perhaps you and I can talk about what your experience has been with lead time required for the non-clinical test product so I can factor that in to building an appropriate task into the schedule. Please give me a call when you have a chance.

Thanks,
Valerie

----Original Message----
From: Nixon, Gerry M.
Sent: Wednesday, April 30, 2003 11:30 AM
To: Schuster, Dave
Cc: King, Valerie A.; Koller, Debbie; Werley, Michael S
Subject: RE: Input to Master Plan Template

Dave,

I would suggest that the Investigator's Brochure (IB) still belongs in Clinical because it is apparently needed for those studies. It is true that someone in Non-Clinical has been writing it (Debbie, Mike, etc.), but I do not believe that it is used for any non-clinical work. Debbie or Mike may help with defining predecessors and timelines for the IB.

The Define Study Objectives and Develop Protocol Summary lines have been in the Clinical schedules for a long time, I believe. There are similar lines in the non-clinical portions of the schedule, but I believe that these Valerie mentions refer to setting up clinical studies. If they are not needed, that is a Clinical call.

As we discussed, there are lines in the non-clinical portions referring to requesting cigarettes and getting them made for non-clinical testing, and there should be similar lines in the Clinical portions, as there is some preparation time and effort needed before the test cigarettes appear at the testing facility.

Gerry

-----Original Message-----
From: Schuster, Dave
Sent: Wednesday, April 30, 2003 10:55 AM
To: Nixon, Gerry M.
Subject: Input to Master Plan Template

Gerry,
I have Val's updates and she has a note that says Clinical does not write Investigator's Brochure, Define Study Objectives and Develop Protocol Summary and therefore believes that it should belong to Non-Clinical. What do you think; should this be in your area? Of course, my question is why has this not been discussed before now?

Dave

Dave Schuster
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